



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant: David R. MacLean
Serial No: 09/550,049
Filed: April 14, 2000
For: SAFETY DEVICE FOR USE
WITH A VIAL

Appeal No.

3763
ATF

Appeal Brief
S. Bryce
4/27/04

APPELLANT' BRIEF ON EX PARTE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a brief for appealing the final rejecting of pending claims 22-27 of the above-identified application.

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Smiths Medical ASD, Inc., which is the successor entity in interest of SIMS Portex Inc., to which the inventor assigned his interest per an Assignment recorded on April 14, 2000 with the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

The one case concurrently being appealed by the real party in interest is application No. 09/920,860 filed September 22, 2003 entitled "Needle Safety Device With Tortuous Path". However, appellant believes that the '860 appeal does not directly affect or be directly affected by or have any bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-21 were presented for prosecution with the filing of the instant application on April 14, 2000. In response to a Restriction Requirement dated August 27, 2002, an election was made to prosecute claims 1-12 based on the species shown in Figs. 1-8. In an Office Action dated November 5, 2002, the examiner further withdrew claims 7-12 from consideration. In an Amendment dated January 20, 2003 in response to the November 5, 2004 Office Action, claims 1 and 5 were amended and claims 23-27 added. An Office Action dated May 6, 2003 rejected claims 1-6, 22-23 and 25-27. In an Amendment filed on August 5, 2003 in response to the May 6, 2003 Office Action, claims 1 and 24 were amended.

In an Office Action dated October 22, 2003, claims 1-6 and 22-27 were finally rejected. In response to the final rejection, a Response was filed on January 12, 2004 with no amendment to any of the claims. An Advisory Action dated February 2, 2004 held that claims 1-6 were allowable in light of the Response, but the rejection of claims 22-27 was maintained. A second response was filed on February 5, 2004 to address the concerns set forth in the Advisory Action dated February 2, 2004. In an Advisory Action dated February 17, 2004, the examiner maintained the rejection of claims 22-27.

The claims at issue in this case and herein on appeal are therefore claims 22-27, as reproduced in Appendix A attached. For the convenience of the Board, allowed claims 1-6 as well as withdrawn claims 7-21 are reproduced in Appendix B of this Appeal Brief.

STATUS OF AMENDMENTS

No Amendment to the claims accompanied the two Responses filed on January 13, 2004 and February 5, 2004 to the final rejection Office Action dated October 22, 2003.

SUMMARY OF THE INVENTION

The instant invention, as set forth in claim 22, relates to a safety device (2) that comprises a collar (4), a neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar and a latch member (20) that extends from the neck in a direction towards the center of the collar. When the collar is placed about a vial (8) and moved towards a hub (28) of the vial until it is adjacent to one end of the hub, the latch member is latched onto the other end of the hub. [Figs. 1-8; page 5, line 15 to page 8, line 14]

Claim 25, similar to claim 22, recites a safety device that comprises a collar (4), a flexible neck (12) extending from the collar, a housing (14) pivotally connected to the end of the neck away from the collar, and a latch member (20) that extends from the neck in a direction towards the center of the collar. For the invention set forth in the claim 25 embodiment, the latch member would continuously bias against the body of a vial (8) when the collar is placed about the vial and moved towards one end of the hub (28) of the vial. The latch member would latch onto another end of the hub when the collar is moved adjacent to the one end of the hub. [Figs. 1-8; page 5, line 15 to page 8, line 14]

The instant invention is therefore directed to a safety device that has a collar that slidably fits onto the body of a vial and is moved toward the hub of the vial, so that when the collar is adjacent to one end of the hub, the latch member at the neck that extends from the collar would latch onto the other end of the hub of the vial to thereby retain the collar to the vial. The housing that is attached to the other end of the neck away from the collar could then be pivoted to cover the needle that extends from the hub of the vial, per defined in claims 24 and 27.

ISSUE

Per the Advisory Action dated February 2, 2004, the examiner noted that claims 1-6 are allowable. Thus, the only claims at issue for this appeal are claims 22-27, which were rejected under 35 U.S.C. 102(b) as being anticipated by Bachman et al. (U.S. patent 5,733,265).

The sole issue presented herein on appeal is therefore whether the anticipation rejection of claims 22-27 under Bachman et al. (Bachman) is sustainable.

GROUPING OF CLAIMS

Claims 22 and 25 are the independent claims under appeal. Accordingly, Appellant respectfully submits that claims 22 and 25 each should be considered independently.

ARGUMENT

"For a prior art reference to anticipate in terms of 35 U.S.C. 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Anticipation under 35 U.S.C. 102(e) requires that "[e]ach and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference". *In re Robertson*, 169 F.3d. 743, 746 (Fed. Cir. 1999).

In rejecting claims 22-27 under 35 U.S.C. 102(b) as being anticipated by Bachman, the examiner relied upon Bachman to show "a collar slidably matable about said [collar]", "a neck member extending from the collar 48", "a housing 32 pivotally connected to the end of the neck member away from the collar", "a latch member 70 extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially the hub". Page 2 of the final rejection Office Action dated October 22, 2003. In the Advisory Action dated February 17, 2004, claim 22 was deemed to be taught by Figs. 1, 4, 12 and 14 of Bachman.

As was pointed out above in the Summary of Invention section, each of claims 22 and 25 recites a collar, a neck extending from the collar, a housing pivotally connected to the end of the neck away from the collar, and a latch member extending from the neck in a direction towards the center of the collar. Moreover, claim 22 specifically recites "wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub", and claim 25 recites "said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one

end of said hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub".

Bachman does not disclose anything close to the safety device set forth in claims 22 or 25. In particular, Bachman does not disclose any collar "placed about a vial and moved toward one end of a hub of a vial". Nor does Bachman disclose any "neck" connecting the collar to a housing, or a "latch member" that extends from the neck.

At best, Bachman discloses a mount 48 that includes an opening 49 that is sized and shaped to receive at least a portion 53 of a needle hub 20 (column 4, lines 62-64; Fig. 1). As shown in Figs. 1 and 3-4, needle hub 20 clearly is not a vial, as it is arranged to be releasably mounted to a syringe via its proximal end 22. It is well understood in the medical art that a syringe is not a vial.

In fact, as best shown by the exploded perspective view of Fig. 1, the needle assembly 10 disclosed by Bachman includes a needle hub 20 to which mount 48 is to be mounted at its distal portion 53. A sheath 32 is connected to mount 48 by a hinge 46 (Figs. 2 and 3). Further, prior to use and for transport, a cover 50 is slid over sheath 32 (Fig. 2). A more detailed overall discussion of the various components of the Bachman needle assembly is provided in column 4, line 45 to column 5, line 23.

The examiner asserts that Bachman discloses "a latch member 70 extending from [sic] the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially adjacent the hub." (Page 2 of the October 22, 2003 Office Action).

In fact, Bachman discloses, or suggests, none of the quoted limitations.

The alleged "latch member 70" in actuality is a proximal raised retention area on the exterior surface 70 of each sidewall 38 of the elongate shield 32 of the needle assembly 10 disclosed by Bachman (column 5, lines 38-43). In fact, retention areas 70 at elongate shield 32 are used to coact with two rails 69 on the inside surface 51 of cover 50 (see rails 69 in Figs. 9 and 10), so as to retain cover 50 onto shield 32 when the needle assembly is being shipped and before use (column 5, lines 43-49). The needle assembly 10 is

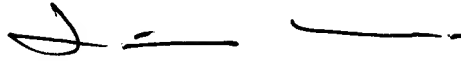
shown in its initial closed position in Figs. 2 and 6. Thus, raised retention areas 70 of elongate shield 32 in actuality have nothing to do with mount 48 for the Bachman device. Putting it simply, component 70 shown in Fig. 1 of Bachman does not coact with anything on mount 48, or needle hub 20, for preventing mount 48 from being removed from needle hub 28. Rather, for the Bachman device, to maintain mount 48 to needle hub 20, an annular groove 78 is formed at the interior surface 79 of mount 48. This annular groove engages a raised projection 21 at needle hub 20, so that mount 48 is retained to needle hub 20 and is rotatable at less than one rotation about needle hub 20 (Fig. 1; column 6, lines 30-40).

Thus, the actual usage of retention areas 70 at elongate shield 32 is to retain cover 50 in shield 32 before the needle assembly is to be used. Given the respective configurations of raised retention areas 70 at elongate shield 32 and rails 69 at the interior surface of cover 50, when the needle assembly is to be used, cover 50 is moved axially in the distal direction. As it is thus moved, a protuberance 73 engages the proximal edge 74 (Figs. 8, 9 and 10) to cause shield 32 to pivot about hinge 46 and move to the open position as shown in Fig. 3 (column 5, lines 38-49). Once cover 50 is removed, elongate shield 32 is pivoted away from needle 12 with a cantilever spring 66 that provides resistance force against elongate shield 32 to thereby prevent the latter from being closed over needle 12, unless a sufficient force is used (column 5, lines 49-55). Needle 12 may then be used.

In sum, Bachman fails to disclose: (1) a vial, (2) a collar that slides over the vial, (3) a latch member extending from the neck member in a direction towards the center of the collar, and (4) when the collar placed about the vial is moved toward a hub [or one end of the hub] of the vial, the latch member would latch onto another end of the hub when the collar is moved adjacent to the one end of the hub. Nothing in Bachman therefore remotely discloses or suggests the claimed invention.

In view of the foregoing, Appellant respectfully submits that the prior art rejection of the being appealed claims 22-27 is without merit and not sustainable. Accordingly, the examiner's rejection of claims 22-27 is respectfully requested to be reversed.

Respectfully submitted,



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APPENDIX A

22. Safety device, comprising:
a collar;
a neck extending from said collar;
a housing pivotably connected to the end of said neck away from said collar; and
a latch member extending from said neck in a direction towards the center of said collar;
wherein when said collar is placed about a vial and moved toward a hub of said vial until adjacent to one end of said hub, said latch member is latched onto another end of said hub.
23. Safety device of claim 22, wherein said latch member is integrated to said neck and flexible relative to said collar.
24. Safety device of claim 22, wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.
25. Safety device, comprising: a collar, a flexible neck extending from said collar, a housing pivotably connected to the end of said neck away from said collar, and a latch member extending from said neck in a direction towards the center of said collar, said latch member continuously biases against body of a vial when said collar is placed about said vial and moved toward one end of a hub of said vial, said latch member further biases against said hub as said collar is moved further toward said one end of said hub, said latch member latching onto another end of said hub when said collar is moved adjacent to said one end of said hub.
26. Safety device of claim 25, wherein said latch member is integrated to said neck and flexible relative to said collar.
27. Safety device of claim 25, wherein said housing comprises at least one integral hook for lockingly gripping a needle extending from said hub when said housing is pivoted to a position in alignment along longitudinal axis of said vial.

APPENDIX B

(Not at issue Claims)

1. (Allowed) Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said hub having a shoulder and a base, said safety device comprising:

a collar slidably matable about said vial, said collar having a distal end;

a neck member extending from the distal end of said collar;

a housing pivotably connected to end of said neck member away from said collar;

and

a latch member extending from said neck member in a direction towards center of said collar, said latch member coacting with the shoulder of said hub and the distal end of said collar coacting with the base of said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and the distal end of said collar is positioned adjacent said hub.

2. (Allowed) Safety device of claim 1, wherein said latch member is integrated to said neck member; and

wherein said neck member is flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

3. (Allowed) Safety device of claim 1, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent to said hub and said latch member is moved into position to latch onto a shoulder of said hub.

4. (Allowed) Safety device of claim 1, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

5. (Allowed) Safety device of claim 4, wherein said locking means comprises a hook integrated to interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

6. (Allowed) Safety device of claim 1, wherein said neck member comprises a flexible upright extending from said collar, and wherein said latch member comprises a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

7. (Withdrawn) Safety device usable with a vial, said vial having mounted to one of its ends a hub from which a needle extends, said safety device comprising:

a collar slidably matable about said vial;

a support member extending from said collar;

a housing pivotably connected to the end of said support member away from said collar; and

a latch member extending from said collar in planar relationship with said support member, said latch member being flexible relative to said support member so as to coact with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved substantially adjacent to said hub.

8. (Withdrawn) Safety device of claim 7, wherein said support member comprises a frame extending from said collar and wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

9. (Withdrawn) Safety device of claim 7, wherein said support member is a rigid member and said latch member comprises a flexible upright extending from said collar and a lip extending at its tip, said lip latching onto a shoulder of said hub when said collar is moved adjacent to said hub.

10. (Withdrawn) Safety device of claim 7, wherein said latch member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said latch member latches onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said latch member from flexing away and disengaged from said hub.

11. (Withdrawn) Safety device of claim 10, wherein said locking means comprises a hook integrated to the interior of said housing for holding said needle fixed relative to said housing once said housing is pivoted to said alignment position and said needle biases and then is held by said hook.

12. (Withdrawn) Safety device of claim 7, wherein said vial further comprises a gasket slidable along the length of said vial, said vial with said collar positioned adjacent said hub being placed into a cavity of a holder, said gasket being coupled to a plunger slidable along the length of said holder;

wherein fluid stored in said vial is ejected out of said vial through said needle when said plunger is pushed towards said hub.

13. (Withdrawn) In combination,

a collar slidably matable about a vial having a hub from which a needle extends;

a neck member extending from said collar;

a housing pivotably connected to the end of said neck member away from said collar,

a latch member positioned relative to said neck member coacting with said hub to prevent said collar from being removed from said vial once said collar has been mated about said vial and moved to be substantially adjacent said hub; and

a holder having a cavity into which said vial having said collar mounted thereabout is fitted.

14. (Withdrawn) Combination of claim 13, wherein said latch member integrally extends from said neck member in a direction towards the center of said collar, said neck member being flexible with respect to said collar so that said latch member is guided along the side of said hub as said collar is moved towards said hub, said latch member latching onto a shoulder of said hub when said collar is moved adjacent said hub.

15. (Withdrawn) Combination of claim 13, wherein said latch member is integrated to a location along said neck member so as to effect a space between said latch member and said collar along said neck member whereinto said hub matingly fits after said collar is moved adjacent said hub and said latch member is moved into position to latch onto a shoulder of said hub.

16. (Withdrawn) Combination of claim 13, wherein said neck member comprises a rigid support frame extending from said collar; and

wherein said latch member extends from said collar to fit within the confines of said support frame, said latch member being guided along said hub as said collar is moved towards said hub and latches onto a shoulder of said hub when said collar is moved adjacent to said hub.

17. (Withdrawn) Combination of claim 13, wherein said neck member is flexible with respect to said collar so that once said collar is moved to a given position relative to said hub, said neck member flexes to a position to enable said latch member to latch onto a shoulder of said hub; and

wherein said housing comprises a slot wherethrough said needle passes when said housing is pivoted to a position in substantial alignment with the longitudinal axis of said vial, said housing further including at least one locking means for fixedly maintaining said needle relative to said housing once said housing is pivoted to said alignment position;

wherein once fixed relative to each other, said needle and said housing interact to prevent said neck member from flexing away from said hub and said latch member from being disengaged from said shoulder of said hub.

18. (Withdrawn) Combination of claim 13, further comprising:
a gasket slidable along the length of said vial;
a plunger slidable along the length of said holder;
wherein said gasket is coupled to said plunger when said vial with said collar positioned adjacent said hub is fitted into said cavity of said holder so as to eject fluid stored in said vial through said needle when said plunger is pushed towards said hub.
19. (Withdrawn) Combination of claim 13, wherein said holder further comprises a turnable base member that, when rotated in one direction, would come into contact with the end of said vial away from said hub to thereby apply a biasing force against said vial to forcibly maintain said vial inside said cavity of said holder and said collar secured to said vial.
20. (Withdrawn) A method of attaching a needle protection housing to a vial, a hub formed at one end of said vial and a needle extending from said hub, comprising the steps of:
attaching said housing to a collar via a neck member;
extending from said neck member a latch member in a direction towards the center of said collar;
fitting said collar about said vial; and
moving said collar relative to said hub until said latch member latches onto a given portion of said hub to prevent said collar from moving away from said hub.
21. (Withdrawn) Method of claim 20, further comprising the steps of:
placing said vial fitted with said collar into a holder;
actuating a mechanism integral of said holder to apply a biasing force to said vial to securely retain said vial within said holder.

CITATIONS

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<i>In re Bond,</i> 910 F.2d 831 (Fed. Cir. 1990)	4
<i>In re Robertson,</i> 169 F.3d. 743 (Fed. Circ. 1999)	4



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FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Sir:

The Commissioner is hereby authorized to debit the amount of \$330.00 from Deposit Account No. 50-0501 for the filing of the accompanying Appeal Brief for the above-identified Application.

The Commissioner is further hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

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Date: April 15, 2004